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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/301,380	06/15/2001	GERALD P. MURPHY	20093A-002100US	5494

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EXAMINER

BOWMAN, AMY HUDSON

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/301,380	MURPHY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Amy H Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3,6,8,22,24-26,34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,6,8,22 and 24-26 is/are rejected.
- 7) ☒ Claim(s) 34 and 35 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

Applicant's response filed 2/9/2005 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 7/28/2004 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 2/9/2005, claims 1, 3, 6, 8, 22, 24, 25, 26, 34 and 35 are pending in the application. Applicant has canceled claims 2, 4, 5, 7, 9-21, 23 and 27-33.

### ***Response to Arguments--Claim Rejections - 35 USC § 112***

Claims 3, 6, 8, and 24 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites a method wherein an oligonucleotide is administered "locally" to a subject, however, it is unclear what the meets and bounds of the term "locally" actually are. Claims 6, 8, and 24 are indefinite for the same reasons due to dependence on claim 3. Claims 25 and 26 are dependent on claim 3, but are not rejected on these grounds because they clarify the location with the requirement that the antisense oligonucleotide be administered directly at the site of

the tumor. This rejection is repeated for the same reasons of record set forth in the official office action mailed 7/28/2004.

In applicant's amendment filed 2/9/2005, applicant traverses the 35 U.S.C. 112, second paragraph rejection set forth in the official office action mailed on 7/28/2004. Applicant argues that the phrase "local administration" is a term of art well known to the clinician as of the filing date of the instant application. Applicant argues that the term refers to forms of administration that make an agent available to a particular area of the body of the subject, as contrasted with "systemic administration", which refers to those forms of administration that make the agent available to the body generally. Applicant argues that a clinician would know which forms of administration are local versus systemic. It is noted that the clinician is not one of ordinary skill in the art.

Applicant's argument has been considered but is not found persuasive. Applicants own argument emphasizes a need to direct the composition to a particular region. For example, applicant references Stedman's Medical Dictionary to define local and systemic administration. However, the current claim language does not reflect this. Although local administration to the tumor may be inferred, the current phrasing of the claim language does not clearly state this. Note that this is not the only possible use for the term local. When viewed from the perspective of one of ordinary skill, subjects may also be in a location since the term "local" most directly modifies the subject. When taken in it's context, the most reasonable interpretation is that "local" modifies the subject rather than the injection site. Therefore, the 35 U.S.C. 112, second paragraph

rejection set forth in the official office action mailed on 7/28/2004 is considered proper and maintained.

***Response to Arguments--Claim Rejections - 35 USC § 102 or 35 USC § 103***

Claims 1 and 22 stand rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lane et al. (of record). This rejection is repeated for the same reasons of record set forth in the official office action mailed 7/28/2004. Claim 31 has been cancelled by applicant, obviating the rejection against claim 31. Lane et al. disclose a 1.1 kb nucleotide in a solution comprising a pharmaceutically acceptable carrier (e.g. water), wherein the nucleotide is fully complementary to SEQ ID NO: 1 of the instant application. Therefore, absent evidence to the contrary, claims 1 and 22 are anticipated by or, in the alternative, obvious over Lane et al. See also MPEP § 2112.

In applicant's amendment filed 2/9/2005, applicant traverses the 35 U.S.C. 102(b)/103(a) rejection set forth in the official office action mailed on 7/28/2004. Applicant argues that for a reference to anticipate a claim under 35 U.S.C. 102(b), the reference must expressly or inherently disclose each and every limitation of the recited claim. Applicant argues that the amendment to claim 1, which adds the term "pharmaceutical", obviates the 35 U.S.C. 102(b)/103(a) rejection set forth in the official office action mailed on 7/28/2004. Additionally, applicant argues that the 1.1 kb nucleic acid disclosed by Lane et al. is disclosed as a probe used in Northern blotting solutions and cannot therefore anticipate pharmaceutical use.

Applicant's argument has been considered but is not found persuasive. Although applicant has traversed the 35 U.S.C. 102(b)/103(a) rejection based on recitation of the term 'pharmaceutical', instant claim 1 is a compound claim in which the recited intended use drawn to pharmaceutical does not provide much patentable weight. As stated in the official office action set forth on 7/28/2004, although Lane et al. disclose their oligonucleotide as a probe, the oligonucleotide disclosed by Lane et al. meets all of the structural limitations of the claimed oligonucleotide, because the oligonucleotide is within the size range of at least 100 nucleotides and is fully complementary to SEQ ID NO: 1, and is in a solution comprising a pharmaceutically acceptable carrier (e.g. water, buffers, etc.). Additionally, applicant argues that motivation or suggestion for modifying the cited reference is necessary to apply a 35 U.S.C. 103(a) rejection. However, this is a 35 U.S.C. 102(b)/103(a) combined rejection that does not require motivation. See MPEP § 2112. Therefore, the 35 U.S.C. 102(b)/103(a) rejection set forth in the official office action mailed on 7/28/2004 is maintained.

***Response to Arguments—Claim Objections***

Claims 25, 26, 34 and 35 stand objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. This objection is repeated for the same reasons of record set forth in the official office action mailed 7/28/2004.

***New Rejections***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 3, 6, 8 and 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention due to the recitation of "an effective amount" in claim 3. The skilled artisan would not understand the metes and bounds of the terminology "an effective amount" due to the lack of clarity regarding what amounts would be effective to accomplish what outcome. It is unclear what the meets and bounds of the terminology "effective amount" are or to what the effective amount is supposed to accomplish. Claims 6, 8 and 24-26 are rejected, as they depend back to claim 3.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755. The examiner can normally be reached on Mon-Fri 7:30 am – 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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